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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/901,362 | 07/09/2001 | Stafford McLean | PC10782A | 5342 |

7590 06/16/2005

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EXAMINER

KIM, VICKIE Y

ART UNIT PAPER NUMBER

1618

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/901,362

Applicant(s)

MCLEAN ET AL.

Examiner

Vickie Kim

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 3-8 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-2 and 9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Status of Application

1. Acknowledgement is made of remarks and argument filed 5/22/2003. There is no amendment made into the claims.
2. Acknowledgement is made of Terminal Disclaimer(TD) filed 5/22/2003. TD is properly entered and Double patenting rejection is withdrawn accordingly.
3. The claims 1-10 are pending and the elected claims 1-2, 9 are presented for the examination.

The claims 3-8 and 10 are maintained as withdrawn since they are considered to be non-elected invention.

Response to Arguments

4. Applicant's arguments filed 5/22/ 2003 have been fully considered but they are not persuasive.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

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In the instant case, applicant argues that WO'565 teaches mu-SSRI combination and fails to teach delta-SSRI combination because naloxone is recognized by those skilled in the art as belong to the mu opioid receptor class. However, as evidenced by US'848, a binding affinity for mu or delta receptors is not based on how skilled artisan perceives but is rather an inherited function where such affinity will be shown naturally when certain amount (high dose) of naloxone is administered. US'848 elucidates biological pathway and also proves that opioid ligand (e.g. naloxone) is effective in alcohol dependence treatment due to its binding activity to delta opioid receptor (see cols. 26-27).

Since the teaching of WO'565 which is directed to a combination of opioid ligand (e.g. naloxone, naltrexone) and SSRI (e.g. sertraline) in the treatment of chemical dependency inherently embraces the scope of the claims and one can readily visualize the delta-SSRI combination from the patented combination, especially because the amount of delta opioid receptor ligand used in both WO'565 (25-150mg daily, see page 6) and instant claims (0.001 to about 500mg/kg per day, see specification at page 9) are overlapping. As stated in WO'565 (see page 8, lines 7-10), sertraline, a selective serotonin reuptake inhibitor, has been shown to significantly reduce the intake of alcohol.

Since US' 905 (Lias) teaches advantages of claimed compound over other opiates in the treatment of chemical dependency due to less side effects that is conventionally known with opiates. Thus one would have been motivated to extend

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WO'595 teaching to substitute opioid ligands(taught in WO565 and US848) with the compound of formula(recited in instant claims) to maximize therapeutic efficacy.

Above references in combination make clear that delta opioid receptor ligand(i.e a compound of formula as recited in claim 1) and SSRI(e.g. sertraline) have been individually used for the treatment of chemical dependency. It is obvious to combine two compositions each of which is taught by prior art to be useful for same purpose; idea of combining them flows logically from their having been individually taught in the prior art. The combination of active ingredient with the same character is merely the additive effect of each individual component. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Thus, the claimed invention is not patentably distinct over the prior art of the record and the detailed rejection is same set forth in previous office action mailed 9/3/2003.

Note: Since 103 rejection is substantially same as previous 103 rejection, the 103 rejection will not be repeated herein.

Conclusion

5. No claim is allowed.
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

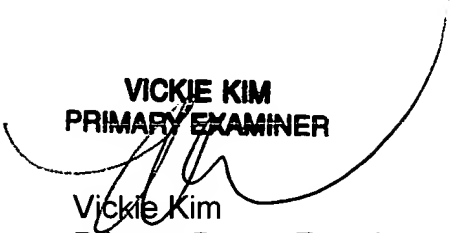
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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VICKIE KIM
PRIMARY EXAMINER



Vickie Kim
Primary Patent Examiner
June 12, 2005
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